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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,490	09/25/2003	Eytan R. Barnea	120785.0310	8761

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	**PAPER NUMBER**
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/670,490	BARNEA ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *9-22 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *9-22 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-8, 23 and 24 have been canceled. Claims 9, 15 and 22 have been amended. Claim 25 has been added. Claims 9-22 and 25 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims drawn to the peptides of SEQ ID NO:1-12 and methods of using said peptides to inhibit the proliferation of cancer cells, would be given priority to 60/091,579, filed July 2, 1998 for the reasons of record set forth in the prior Office action.

Claims 9-22 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 22 is drawn to the peptides of SEQ ID NO:1-12. Claim 25 is drawn to composition comprising said peptides.. When given the broadest reasonable interpretation the claims can include peptides comprising SEQ ID NO:1-12 rather than consisting of said peptides. Thus the genus of antiproliferative peptides is variant because said genus tolerates members which only minimally comprise SEQ ID NO:1-12, thus requiring only 7 amino acids of the described peptides and some degree of antiproliferative property to be included within the genus. Further, the genus is not limited by a functional attribute common to all members of the genus. The description of the peptides consisting of SEQ ID NO:1-12 fails to describe the claimed genus because the genus tolerates members which differ widely in structure and function from the instant SEQ ID NO:1-12 because 7 contiguous amino acids could be dominated by a much larger peptide having completely different mechanism of exerting an antiproliferative action that that of the instant SEQ IDNO:1-12. One of skill in the art would reasonable conclude that applicant was not in possession of the genus of peptides consisting of SEQ ID NO:1-12 and

therefore was not in possession of methods reliant on said genus. Amendment of claim 22 to read unambiguously on peptides consisting of SEQ ID NO:1-12 would overcome this rejection.

Applicant argues that the claims now encompass the recited sequences and do not include any larger or smaller sequences. This has been considered but not found persuasive. The language of "a peptide having a sequence" is the same as a peptide "comprising a sequence" and is thus open language.

Claims 9-22 and 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for inhibiting the proliferation of cancer cells or virally infected cells comprising the administration of the peptides consisting of SEQ ID NO:2, 3 or 8, does not reasonably provide enablement for a method of using SEQ ID NO:1, 4-7 or 9-12. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification states that the mixture of peptides corresponding to SEQ ID NO:1-12 possessed no inhibitory activity against MCF-7 cells, but that SEQ ID NO:2, 3and 8 possessed significant inhibitory activity, and explains that the remainder of the peptides are able to compete with the active peptides for receptor sites on MCF-7, but do not possess inhibitory activity (page 26, line 22 to page 27, line 13). Thus is appears that SEQ ID NO:1, 4-7 and 9-12 are not antiproliferative peptides having activity against cancer cells or virally infected cells. One of skill in the art would be subject to undue experimentation in order to carry out the method of claim 9-21 with peptides other than SEQ ID NO:2, 3 or 8. One of skill in the art would also be subject to undue experimentation in order to use the peptides SEQ ID NO:1, 4-7 and 9-12 of claims 22 and 25 because said peptides would not be expected to have anti-proliferative activity and the instant specification has not provided any alternative teachings regarding how to use the claimed peptides.

Claims 9-11, 14, 22 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Barnea (U.S. 5,648,340, cited in the previous action).

Claims 22 and 25 are drawn to an isolated peptide selected from the group consisting of SEQ ID NO:1-12 and a composition comprising an excipient and an isolated peptide having a

sequence selected from SEQ ID NO:1-12, and combinations thereof. Claim 9 is drawn to a method of inhibiting the proliferation of cancer cells in a subject comprising administering to said subject an effective amount of a peptide elected from the group consisting of SEQ ID NO:1-12 and combinations thereof. Claims 10, 11, 13 and 14 specify that the cancer cells are breast, lung, melanoma and leukemia cells, respectively. Barnea discloses an antiproliferative embryonic fraction having a molecular weight of less than 8 kDa (column 18, Table III). Barnea et al discloses that the embryonic tissue is solublized by sonication, subjected to centrifugation to remove cellular debris (column 7, lines 43-51). Barnea discloses that the resulting supernatant is then fractionated by molecular weight, using as an example, a gel filtration system (column 7, lines 54-59). Barnea discloses a separation step comprising a DEAE column (column 20, lines 56-61). The anti-proliferative fraction of Barnea would inherently comprise a peptide of SEQ ID NO:1-12 because the material from whence the instant SEQ ID NO:1-12 were obtained is the same as that of the material used for the antiproliferative fraction of Barnea. Barnea discloses a method for treating cancer in a patient including breast, ovary, kidney, lung brain intestine, bone marrow, lympho-reticulo, stomach esophagus, pancreas, spinal cord mucosa, germ cell, bone, muscle, melanoma and choriocarcinoma (column 11, lines 29-35). The disclosure of lympho-reticulo cancers fulfills the specific embodiment of leukemia. Barnes et al disclose that the less than 8kDa extract in a pharmaceutically acceptable carrier (claim 2).

Applicant argues that Barnea et al do not disclose the isolated peptides of the invention and that the low molecular weight extract comprised more than just the instant claimed peptides and therefore cannot meet the limitation of "isolated". This has been considered but not found persuasive. The term "isolated" reads on any degree of isolation, and in the case of Barnea et al, the low molecular weight extract which comprises the peptides fulfills the embodiments of "isolated" in that the low molecular weight extract has been isolated and somewhat purified from that found in nature.

All other rejections and objections as set forth in the prior Office action are withdrawn in light of applicants amendments.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KAREN A. CANELLA, PH.D.
PRIMARY EXAMINER

Karen A. Canella, Ph.D.
01/21/2007